

PCT
NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Assistant Commissioner for Patents
United States Patent and Trademark
Office
Box PCT
Washington, D.C.20231
ÉTATS-UNIS D'AMÉRIQUE

in its capacity as elected Office

Date of mailing:

21 October 1999 (21.10.99)

International application No.:

PCT/US98/24458

Applicant's or agent's file reference:

HUM093WOPT02

International filing date:

17 November 1998 (17.11.98)

Priority date:

19 November 1997 (19.11.97)

Applicant:

WEEKS, Charles, E.

1. The designated Office is hereby notified of its election made:



in the demand filed with the International preliminary Examining Authority on:

23 April 1999 (23.04.99)



in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was


was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

Authorized officer:

J. Zahra

Telephone No.: (41-22) 338.83.38

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

REC'D 02 NOV 1999

WIPO

PCT

| | | |
|--|--|---|
| Applicant's or agent's file reference HUM093WOPT02 | FOR FURTHER ACTION | See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) |
| International application No. PCT/US98/24458 | International filing date (day/month/year) 17 NOVEMBER 1998 | Priority date (day/month/year) 19 NOVEMBER 1997 |
| International Patent Classification (IPC) or national classification and IPC IPC(6): A01N 45/00; A61K 31/56 and US Cl.: 514/169, 177, 178, 179, 180, 181, 182 | | |
| Applicant HUMANETICS CORPORATION | | |

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 0 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of report with regard to novelty, inventive step or industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

| | |
|--|--|
| Date of submission of the demand 23 APRIL 1999 | Date of completion of this report 06 OCTOBER 1999 |
| Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 | Authorized officer FREDERICK KRASS |
| Facsimile No. (703) 305-3230 | Telephone No. (703) 308-2351 |

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US98/24458

I. Basis of the report

1. This report has been drawn on the basis of *(Substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments):*

☒ the international application as originally filed.

☒ the description, pages 1-11, as originally filed.

pages NONE, filed with the demand.

pages NONE, filed with the letter of _____.

pages _____, filed with the letter of _____.

☒ the claims, Nos. 1-21, as originally filed.

Nos. NONE, as amended under Article 19.

Nos. NONE, filed with the demand.

Nos. NONE, filed with the letter of _____.

Nos. _____, filed with the letter of _____.

☒ the drawings, sheets/fig NONE, as originally filed.

sheets/fig NONE, filed with the demand.

sheets/fig NONE, filed with the letter of _____.

sheets/fig _____, filed with the letter of _____.

2. The amendments have resulted in the cancellation of:

☒ the description, pages NONE.

☒ the claims, Nos. NONE.

☒ the drawings, sheets/fig NONE.

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the ~~Supplemental Box~~ Additional observations below (Rule 70.2(c)).

4. Additional observations, if necessary:

NONE

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US98/24458

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. STATEMENT**

| | | |
|-------------------------------|--------------------|-----|
| Novelty (N) | Claims <u>1-21</u> | YES |
| | Claims <u>NONE</u> | NO |
| Inventive Step (IS) | Claims <u>NONE</u> | YES |
| | Claims <u>1-21</u> | NO |
| Industrial Applicability (IA) | Claims <u>1-21</u> | YES |
| | Claims <u>NONE</u> | NO |

2. CITATIONS AND EXPLANATIONS

Claims 1-21 meet the criteria set out under PCT Article 33(2) Novelty.

Claims 1-21 lack an inventive step under PCT Article 33(3) as being obvious over HENRY A. LARDY in view of RAYMOND F. PEAT. The claimed androsterones are known immunomodulators as taught by HENRY A. LARDY; since it is generally known to use androsterones to treat arthritis and joint disabilities as taught by RAYMOND F. PEAT, it would have been obvious to have used the claimed androsterones for that purpose, based on the expectation that steroids having closely related structures can be expected to function in a biochemically and physiologically equivalent manner.

Claims 1-21 meet the criteria set out in PCT Article 33(4) the applicability of the claimed methods to the pharmaceutical/medical industries is self-evident.

----- NEW CITATIONS -----
NONE

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/24458

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : A01N 45/00; A61K 31/56

US CL : 514/169, 177, 178, 179, 180, 181, 182

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 514/169, 177, 178, 179, 180, 181, 182

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|-----------|---|-----------------------|
| Y | Chemical Abstract, Volume 106, abstract No. 143992, RAYMOND F. PEAT, "Pharmaceutical Compositions Containing Dehydroepiandrosterone and other Anesthetic Steroids in the Treatment of Arthritis and Other Joint Disabilities", US 4,528,052 A, 09 December 1986, see entire abstract. | 1-21 |
| Y | Chemical Abstract, Volume 126, abstract No. 113708, HENRY A. LARDY, "Treatment of Immune System With .DELTA.5 Androsterones", US 5,585,371 A, 17 December 1996, see entire abstract. | 1-21 |



Further documents are listed in the continuation of Box C.



See patent family annex.

| | |
|---|--|
| * Special categories of cited documents: | *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention |
| *A* document defining the general state of the art which is not considered to be of particular relevance | *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone |
| *B* earlier document published on or after the international filing date | *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art |
| *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) | *A* document member of the same patent family |
| *O* document referring to an oral disclosure, use, exhibition or other means | |
| *P* document published prior to the international filing date but later than the priority date claimed | |

Date of the actual completion of the international search

12 JANUARY 1999

Date of mailing of the international search report

25 JAN 1999

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
BOSTON

Authorized officer

D. Lawrence
FREDERICK J. LAWRENCE

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

MICHAEL S. SHERRILL
MICHAEL S. SHERRILL LAW OFFICES
4756 BANNING AVENUE, SUITE 200
WHITE BEAR LAKE MN 55110-3205

PCT/PCT Rec'd 19 MAY 2000

RECEIVED
PCT

MAY 21 1999
NOTIFICATION OF RECEIPT
OF DEMAND

MICHAEL SHERRILL LAW OFFICES

(PCT Rule 8.1(b), first sentence
and Administrative Instructions, Section 601)

Date of mailing
(day/month/year)

17 MAY 1999

Applicant's or agent's file reference
HUM093WOPT02

IMPORTANT NOTIFICATION

International application No.
PCT/US98/24458

International filing date (day/month/year)
17 NOV 98

Priority date (day/month/year)
19 NOV 97

Applicant

HUMANETICS CORPORATION

1. The applicant is hereby notified that this International Preliminary Examining Authority considers the following date as the date of receipt of the demand for international preliminary examination of the international application:

23 Apr 99

2. This date of receipt is:

☒

the actual date of receipt of the demand.

☐

the date on which the proper corrections to the demand were timely received.

3. ☐ This date is **AFTER** the expiration of 19 months from the priority date.

Attention: The election(s) made in the demand does (do) not have the effect of postponing the commencement of the national phase until 30 months from the priority date (or later in some Offices) (Article 39(1)). Therefore, the acts for entry into the national phase must be performed within 20 months from the priority date (or later in some Offices) (Article 22).

For details, see Annex B to Form PCT/IB/301 sent by the International Bureau and Volume II of the PCT Applicant's Guide.

☐

This notification confirms the information given in person or by telephone on:

4. Only where paragraph 3 applies, a copy of this notification has been sent to the International Bureau.

Name and mailing address of the IPEA/US
Assistant Commissioner for Patents
Box PCT
Washington, D.C. 20231
Facsimile No.

Attn: IPEA/US

Authorized officer

SIGMUND HOSTAD
INTERNATIONAL DIVISION
703-305-3680

Telephone No.

CT

REQUEST

The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty.

For receiving Office use only

International Application No.

International Filing Date

Name of receiving Office and "PCT International Application"

Applicant's or agent's file reference
(if desired) (12 characters maximum) HUM093WOPT02

Box No. I TITLE OF INVENTION

USE OF Δ 5-ANDROSTENE-3 β -OL-7,17-DIONE IN THE TREATMENT OF ARTHRITIS

Box No. II APPLICANT

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)

HUMANETICS CORPORATION
Interchange Tower
600 South Highway 169, Suite 1205
St. Louis Park, Minnesota 55426-1205
US

☐ This person is also inventor.Telephone No.
(612) 513-9246Facsimile No.
(612) 513-9049

Teleprinter No.

State (that is, country) of nationality:
USState (that is, country) of residence:
US

This person is applicant for the purposes of: ☐ all designated States ☒ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box

Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)

WEEKS, Charles E.
5276 Lakeview Avenue
White Bear Lake, Minnesota 55110
US

This person is:

☐ applicant only☒ applicant and inventor☐ inventor only (If this check-box is marked, do not fill in below.)State (that is, country) of nationality:
USState (that is, country) of residence:
US

This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicated in the Supplemental Box

☐ Further applicants and/or (further) inventors are indicated on a continuation sheet.

Box No. IV AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE

The person identified below is hereby/has been appointed to act on behalf of the applicant(s) before the competent International Authorities as:

☒ agent ☐ common representative

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)

SHERRILL, Michael S.
MICHAEL S. SHERRILL LAW OFFICES
4756 Banning Avenue, Suite 200
White Bear Lake, Minnesota 55110-3205
US

Telephone No.
(651) 426-2400Facsimile No.
(651) 426-2322

Teleprinter No.

☐ Address for correspondence: Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.

Box No.V D N OF STATES

The following designations are hereby made under Rule 4.9(a) (mark the applicable check-boxes; at least one must be marked):

Regional Patent

- ☐ AP ARIPO Patent: GH Ghana, GM Gambia, KE Kenya, LS Lesotho, MW Malawi, SD Sudan, SZ Swaziland, UG Uganda, ZW Zimbabwe, and any other State which is a Contracting State of the Harare Protocol and of the PCT
- ☐ EA Eurasian Patent: AM Armenia, AZ Azerbaijan, BY Belarus, KG Kyrgyzstan, KZ Kazakhstan, MD Republic of Moldova, RU Russian Federation, TJ Tajikistan, TM Turkmenistan, and any other State which is a Contracting State of the Eurasian Patent Convention and of the PCT
- ☒ EP European Patent: AT Austria, BE Belgium, CH and LI Switzerland and Liechtenstein, CY Cyprus, DE Germany, DK Denmark, ES Spain, FI Finland, FR France, GB United Kingdom, GR Greece, IE Ireland, IT Italy, LU Luxembourg, MC Monaco, NL Netherlands, PT Portugal, SE Sweden, and any other State which is a Contracting State of the European Patent Convention and of the PCT
- ☐ OA OAPI Patent: BF Burkina Faso, BJ Benin, CF Central African Republic, CG Congo, CI Côte d'Ivoire, CM Cameroon, GA Gabon, GN Guinea, ML Mali, MR Mauritania, NE Niger, SN Senegal, TD Chad, TG Togo, and any other State which is a member State of OAPI and a Contracting State of the PCT (if other kind of protection or treatment desired, specify on dotted line)

National Patent (if other kind of protection or treatment desired, specify on dotted line):

- | | |
|---|---|
| <input type="checkbox"/> AL Albania | <input type="checkbox"/> LS Lesotho |
| <input type="checkbox"/> AM Armenia | <input type="checkbox"/> LT Lithuania |
| <input type="checkbox"/> AT Austria | <input type="checkbox"/> LU Luxembourg |
| <input checked="" type="checkbox"/> AU Australia | <input type="checkbox"/> LV Latvia |
| <input type="checkbox"/> AZ Azerbaijan | <input type="checkbox"/> MD Republic of Moldova |
| <input type="checkbox"/> BA Bosnia and Herzegovina | <input type="checkbox"/> MG Madagascar |
| <input type="checkbox"/> BB Barbados | <input type="checkbox"/> MK The former Yugoslav Republic of Macedonia |
| <input type="checkbox"/> BG Bulgaria | <input type="checkbox"/> MN Mongolia |
| <input type="checkbox"/> BR Brazil | <input type="checkbox"/> MW Malawi |
| <input type="checkbox"/> BY Belarus | <input type="checkbox"/> MX Mexico |
| <input checked="" type="checkbox"/> CA Canada | <input type="checkbox"/> NO Norway |
| <input type="checkbox"/> CH and LI Switzerland and Liechtenstein | <input type="checkbox"/> NZ New Zealand |
| <input type="checkbox"/> CN China | <input type="checkbox"/> PL Poland |
| <input type="checkbox"/> CU Cuba | <input type="checkbox"/> PT Portugal |
| <input type="checkbox"/> CZ Czech Republic | <input type="checkbox"/> RO Romania |
| <input type="checkbox"/> DE Germany | <input type="checkbox"/> RU Russian Federation |
| <input type="checkbox"/> DK Denmark | <input type="checkbox"/> SD Sudan |
| <input type="checkbox"/> EE Estonia | <input type="checkbox"/> SE Sweden |
| <input type="checkbox"/> ES Spain | <input type="checkbox"/> SG Singapore |
| <input type="checkbox"/> FI Finland | <input type="checkbox"/> SI Slovenia |
| <input type="checkbox"/> GB United Kingdom | <input type="checkbox"/> SK Slovakia |
| <input type="checkbox"/> GE Georgia | <input type="checkbox"/> SL Sierra Leone |
| <input type="checkbox"/> GH Ghana | <input type="checkbox"/> TJ Tajikistan |
| <input type="checkbox"/> GM Gambia | <input type="checkbox"/> TM Turkmenistan |
| <input type="checkbox"/> GW Guinea-Bissau | <input type="checkbox"/> TR Turkey |
| <input type="checkbox"/> HR Croatia | <input type="checkbox"/> TT Trinidad and Tobago |
| <input type="checkbox"/> HU Hungary | <input type="checkbox"/> UA Ukraine |
| <input type="checkbox"/> ID Indonesia | <input type="checkbox"/> UG Uganda |
| <input type="checkbox"/> IL Israel | <input checked="" type="checkbox"/> US United States of America |
| <input type="checkbox"/> IS Iceland | <input type="checkbox"/> UZ Uzbekistan |
| <input type="checkbox"/> JP Japan | <input type="checkbox"/> VN Viet Nam |
| <input type="checkbox"/> KE Kenya | <input type="checkbox"/> YU Yugoslavia |
| <input type="checkbox"/> KG Kyrgyzstan | <input type="checkbox"/> ZW Zimbabwe |
| <input type="checkbox"/> KP Democratic People's Republic of Korea | |
| <input type="checkbox"/> KR Republic of Korea | |
| <input type="checkbox"/> KZ Kazakhstan | |
| <input type="checkbox"/> LC Saint Lucia | |
| <input type="checkbox"/> LK Sri Lanka | |
| <input type="checkbox"/> LR Liberia | |

Check-boxes reserved for designating States (for the purposes of a national patent) which have become party to the PCT after issuance of this sheet:

Precautionary Designation Statement: In addition to the designations made above, the applicant also makes under Rule 4.9(b) all other designations which would be permitted under the PCT except any designation(s) indicated in the Supplemental Box as being excluded from the scope of this statement. The applicant declares that those additional designations are subject to confirmation and that any designation which is not confirmed before the expiration of 15 months from the priority date is to be regarded as withdrawn by the applicant at the expiration of that time limit. (Confirmation of a designation consists of the filing of a notice specifying that designation and the payment of the designation and confirmation fees. Confirmation must reach the receiving Office within the 15-month time limit.)

| Box No. VI CLAIM | | Where earlier application is: | | |
|---|-------------------------------|-------------------------------|---------------------------------------|---|
| Filing date of earlier application (day/month/year) | Number of earlier application | national application: country | regional application: regional Office | international application: receiving Office |
| item (1) 19 November 1997 | 60/066,197 | United States | | |
| item (2) | | | | |
| item (3) | | | | |

☒ The receiving Office is requested to prepare and transmit to the International Bureau a certified copy of the earlier application(s) (only if the earlier application was filed with the Office which for the purposes of the present international application is the receiving Office) identified above as item(s): (1)
 * Where the earlier application is an ARIPO application, it is mandatory to indicate in the Supplemental Box at least one country party to the Paris Convention for the Protection of Industrial Property for which that earlier application was filed (Rule 4.10(b)(ii)). See Supplemental Box.

Box No. VII INTERNATIONAL SEARCHING AUTHORITY

Choice of International Searching Authority (ISA)
 (if two or more International Searching Authorities are competent to carry out the international search, indicate the Authority chosen; the two-letter code may be used):

Request to use results of earlier search; reference to that search (if an earlier search has been carried out by or requested from the International Searching Authority):

Date (day/month/year) Number Country (or regional Office)

ISA/US

Box No. VIII CHECK LIST: LANGUAGE OF FILING

| | |
|---|--|
| This international application contains the following number of sheets: request : 3 description (excluding sequence listing part) : 11 claims : 3 abstract : 1 drawings : 0 sequence listing part of description : 0 Total number of sheets : 18 | This international application is accompanied by the item(s) marked below: 1. <input checked="" type="checkbox"/> fee calculation sheet 2. <input checked="" type="checkbox"/> separate signed power of attorney 3. <input checked="" type="checkbox"/> copy of general power of attorney; reference number, if any: HUM093WOPT02 4. <input type="checkbox"/> statement explaining lack of signature 5. <input type="checkbox"/> priority document(s) identified in Box No. VI as item(s): 6. <input type="checkbox"/> translation of international application into (language): 7. <input type="checkbox"/> separate indications concerning deposited microorganism or other biological material 8. <input type="checkbox"/> nucleotide and/or amino acid sequence listing in computer readable form 9. <input checked="" type="checkbox"/> other (specify): Transmittal Letter, Return Postcard |
|---|--|

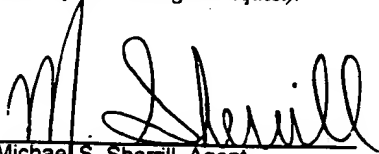
Figure of the drawings which should accompany the abstract:

Language of filing of the international application:

English

Box No. IX SIGNATURE OF APPLICANT OR AGENT

Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the request).


 Michael S. Sherrill, Agent

| | | |
|---|---|--|
| For receiving Office use only | | 2. Drawings: <input type="checkbox"/> received: <input type="checkbox"/> not received: |
| 1. Date of actual receipt of the purported international application: | | |
| 3. Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application: | | |
| 4. Date of timely receipt of the required corrections under PCT Article 11(2): | | |
| 5. International Searching Authority (if two or more are competent): ISA/ | 6. <input type="checkbox"/> Transmittal of search copy delayed until search fee is paid | |

| |
|---|
| For International Bureau use only |
| Date of receipt of the record copy by the International Bureau: |

RECEIVED
JUL 06 1999

PATENT COOPERATION TREATY

PCT/US98/244E

MICHAEL SHERRILL LAW OFFICES PCT 19 MAY 2000

NOTIFICATION OF THE RECORDING
OF A CHANGE

(PCT Rule 92bis.1 and
Administrative Instructions, Section 422)

From the INTERNATIONAL BUREAU

To:

SHERRILL, Michael, S.
Michael S. Sherrill Law Offices
Suite 200
4756 Banning Avenue
White Bear Lake, MN 55110-3205
ÉTATS-UNIS D'AMÉRIQUE

| | |
|---|---|
| Date of mailing (day/month/year) 29 June 1999 (29.06.99) | IMPORTANT NOTIFICATION |
| Applicant's or agent's file reference HUM093WOPT02 | |
| International application No. PCT/US98/24458 | International filing date (day/month/year) 17 November 1998 (17.11.98) |

1. The following indications appeared on record concerning:

☒ the applicant ☐ the inventor ☐ the agent ☐ the common representative

| | | |
|---|----------------------------|--------------------------|
| Name and Address HUMANETICS CORPORATION Interchange Tower Suite 1205 600 South Highway 169 St. Louis Park, MN 55426-1205 United States of America | State of Nationality US | State of Residence US |
| | Telephone No. | |
| | Facsimile No. | |
| | Teleprinter No. | |

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

☐ the person ☐ the name ☒ the address ☐ the nationality ☐ the residence

| | | |
|---|----------------------------|--------------------------|
| Name and Address HUMANETICS CORPORATION 18894 Lake Drive East Chanhassen, MN 55317 United States of America | State of Nationality US | State of Residence US |
| | Telephone No. | |
| | Facsimile No. | |
| | Teleprinter No. | |

3. Further observations, if necessary:

4. A copy of this notification has been sent to:

☒ the receiving Office ☐ the designated Offices concerned
☐ the International Searching Authority ☒ the elected Offices concerned
☒ the International Preliminary Examining Authority ☐ other:

| | |
|---|-------------------------------|
| The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland | Authorized officer H. Zhou |
|---|-------------------------------|

Facsimile No.: (41-22) 740 14 25

Telephone No.: (41-22) 239 92 29

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

NOV 07 1999

PCT

SHERRILL LAW OFFICES

To: MICHAEL S. SHERRILL
MICHAEL S. SHERRILL LAW OFFICES
4756 BANNING AVENUE, SUITE 200
WHITE BEAR LAKE, MINNESOTA 55110-3205

NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of Mailing
(day/month/year)

27 OCT 1999

Applicant's or agent's file reference

HUM093WOPT02

IMPORTANT NOTIFICATION

International application No.

PCT/US98/24458

International filing date (day/month/year)

17 NOVEMBER 1998

Priority Date (day/month/year)

19 NOVEMBER 1997

Applicant

HUMANETICS CORPORATION

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.
4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/US

Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Authorized officer

FREDERICK KRASS

Form PCT/IB/301 (1997) 305 0000

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

| | | |
|--|---|--|
| Applicant's or agent's file reference HUM093WOPT02 | FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) | |
| International application No. PCT/US98/24458 | International filing date (day/month/year) 17 NOVEMBER 1998 | Priority date (day/month/year) 19 NOVEMBER 1997 |
| International Patent Classification (IPC) or national classification and IPC IPC(6): A01N 45/00; A61K 31/56 and US Cl.: 514/169, 177, 178, 179, 180, 181, 182 | | |
| Applicant HUMANETICS CORPORATION | | |

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 0 sheets.

3. This report contains indications relating to the following items:

I ☒ Basis of the report

II ☐ Priority

III ☐ Non-establishment of report with regard to novelty, inventive step or industrial applicability

IV ☐ Lack of unity of invention

V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

VI ☐ Certain documents cited

VII ☐ Certain defects in the international application

VIII ☐ Certain observations on the international application

| | |
|--|---|
| Date of submission of the demand 23 APRIL 1999 | Date of completion of this report 06 OCTOBER 1999 |
| Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 | Authorized officer FREDERICK KRASS Telephone No. (703) 308-2351 |

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US98/24458

I. Basis of the report

1. This report has been drawn on the basis of *(Substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments):*

☒ the international application as originally filed.

☒ the description, pages 1-11, as originally filed.

pages NONE, filed with the demand.

pages NONE, filed with the letter of _____.

pages _____, filed with the letter of _____.

☒ the claims, Nos. 1-21, as originally filed.

Nos. NONE, as amended under Article 19.

Nos. NONE, filed with the demand.

Nos. NONE, filed with the letter of _____.

Nos. _____, filed with the letter of _____.

☒ the drawings, sheets/fig NONE, as originally filed.

sheets/fig NONE, filed with the demand.

sheets/fig NONE, filed with the letter of _____.

sheets/fig _____, filed with the letter of _____.

2. The amendments have resulted in the cancellation of:

☒ the description, pages NONE.

☒ the claims, Nos. NONE.

☒ the drawings, sheets/fig NONE.

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the ~~Supplemental Box~~ Additional observations below (Rule 70.2(c)).

4. Additional observations, if necessary:

NONE

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US98/24458

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. STATEMENT**

| | | |
|-------------------------------|--------------------|-----|
| Novelty (N) | Claims <u>1-21</u> | YES |
| | Claims <u>NONE</u> | NO |
| Inventive Step (IS) | Claims <u>NONE</u> | YES |
| | Claims <u>1-21</u> | NO |
| Industrial Applicability (IA) | Claims <u>1-21</u> | YES |
| | Claims <u>NONE</u> | NO |

2. CITATIONS AND EXPLANATIONS

Claims 1-21 meet the criteria set out under PCT Article 33(2) Novelty.

Claims 1-21 lack an inventive step under PCT Article 33(3) as being obvious over HENRY A. LARDY in view of RAYMOND F. PEAT. The claimed androsterones are known immunomodulators as taught by HENRY A. LARDY; since it is generally known to use androsterones to treat arthritis and joint disabilities as taught by RAYMOND F. PEAT, it would have been obvious to have used the claimed androsterones for that purpose, based on the expectation that steroids having closely related structures can be expected to function in a biochemically and physiologically equivalent manner.

Claims 1-21 meet the criteria set out in PCT Article 33(4) the applicability of the claimed methods to the pharmaceutical/medical industries is self-evident.

----- NEW CITATIONS -----
NONE

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To: MICHAEL S. SHERRILL
MICHAEL S. SHERRILL LAW OFFICES
4756 BANNING AVENUE, SUITE 200
WHITE BEAR LAKE, MINNESOTA 55110-3205

PTO/PCT Rec'd 19 MAY 2000

RECEIVED
PCT DEC 31 1999

NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

| | | |
|--|---|---|
| Date of Mailing (day/month/year) | | 27 DEC 1999 |
| Applicant's or agent's file reference HUM093WOPT02 | | IMPORTANT NOTIFICATION |
| International application No. PCT/US98/24458 | International filing date (day/month/year) 17 NOVEMBER 1998 | Priority Date (day/month/year) 19 NOVEMBER 1997 |
| Applicant HUMANETICS CORPORATION | | |

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.
4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer
FREDERICK KRASS

Telephone No. (703) 308-2351

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

| | | |
|---|---|---|
| Applicant's or agent's file reference HUM093WOPT02 | FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) | |
| International application No. PCT/US98/24458 | International filing date (day/month/year) 17 NOVEMBER 1998 | Priority date (day/month/year) 19 NOVEMBER 1997 |
| International Patent Classification (IPC) or national classification and IPC IPC(6): A01N 45/00; A61K 31/56 and US Cl.: 514/169, 177, 178, 179, 180, 181, 182 | | |
| Applicant HUMANETICS CORPORATION | | |

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

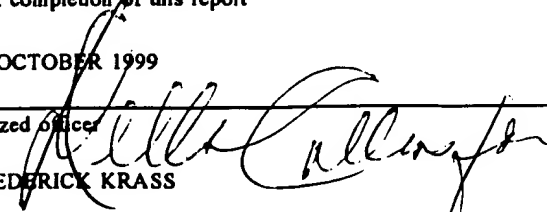
2. This REPORT consists of a total of 4 sheets.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 0 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of report with regard to novelty, inventive step or industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

| | |
|--|--|
| Date of submission of the demand 23 APRIL 1999 | Date of completion of this report 06 OCTOBER 1999 |
| Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 | Authorized officer  FREDERICK KRASS |

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US98/24458

I. Basis of the report

1. This report has been drawn on the basis of *(Substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments)*:

☒ the international application as originally filed.

☒ the description, pages 1-11, as originally filed.
 pages NONE, filed with the demand.
 pages NONE, filed with the letter of _____
 pages _____, filed with the letter of _____

☒ the claims, Nos. 1-21, as originally filed.
 Nos. NONE, as amended under Article 19.
 Nos. NONE, filed with the demand.
 Nos. NONE, filed with the letter of _____
 Nos. _____, filed with the letter of _____

☒ the drawings, sheets/fig NONE, as originally filed.
 sheets/fig NONE, filed with the demand.
 sheets/fig NONE, filed with the letter of _____
 sheets/fig _____, filed with the letter of _____

2. The amendments have resulted in the cancellation of:

☒ the description, pages NONE

☒ the claims, Nos. NONE

☒ the drawings, sheets/fig NONE

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box Additional observations below (Rule 70.2(c)).

4. Additional observations, if necessary:

NONE

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US98/24458

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. STATEMENT**

| | | |
|-------------------------------|--------------------|-----|
| Novelty (N) | Claims <u>1-21</u> | YES |
| | Claims <u>NONE</u> | NO |
| Inventive Step (IS) | Claims <u>1-21</u> | YES |
| | Claims <u>NONE</u> | NO |
| Industrial Applicability (IA) | Claims <u>1-21</u> | YES |
| | Claims <u>NONE</u> | NO |

2. CITATIONS AND EXPLANATIONS

Claims 1-21 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest using the claimed androstene diones to treat arthritis.

Claims 1-21 meet the criteria set out in PCT Article 33(4); the applicability of the claimed methods to the pharmaceutical/medical industries is self-evident.

_____ NEW CITATIONS _____
NONE

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US98/24458

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

Sheet 10